K112048

DEC 16 2011

Meridian Bioscience, Inc.	K112048: Request for Additional Information Attachment 009: Revised 510(k) Summary			
	Product Information:	ImmunoCard *C. difficile* GDH		
	Date:	November 29, 2011	Document Revision:	002

510(k) number: _____ **Date of Preparation:** July 15, 2011

Submitter:	**Meridian Bioscience, Inc**
Submitter's address:	3471 River Hills Drive Cincinnati, Ohio 45244
Contact:	Susan Bogar
Contact number:	(513) 271-3700
Device name:	ImmunoCard *C. difficile* GDH
Common name:	Enzyme Immunoassay for *C. difficile* Common Antigen
Classification:	Antigen, *C. difficile* MCB, CFR Section 866.2660
Predicate device:	K053572: TECHLAB C. DIFF QUIK CHEK®
Reference comparator:	Bacterial culture

Description of the device:

ImmunoCard *C. difficile* GDH is a rapid qualitative enzyme immunoassay screening test to detect *Clostridium difficile* antigen, glutamate dehydrogenase (GDH), in fecal specimens from persons suspected of having *C. difficile* infection. The assay consists of ImmunoCard *C. difficile* GDH Test Cards containing immobilized polyclonal anti-*C. difficile* GDH antibodies, ImmunoCard *C. difficile* GDH Positive Control, ImmunoCard *C. difficile* GDH Sample Diluent/Negative Control, ImmunoCard *C. difficile* GDH Enzyme Conjugate, ImmunoCard Wash Buffer I, and ImmunoCard Substrate I.

Intended Use:

ImmunoCard *C. difficile* GDH is a rapid qualitative enzyme immunoassay screening test to detect *Clostridium difficile* antigen, glutamate dehydrogenase, in fecal specimens from persons suspected of having *C. difficile* infection (CDI). This test does not distinguish between toxigenic and non-toxigenic strains of *C. difficile*. Samples from patients that produce positive results with this test must be further tested with an assay designed to detect toxigenic *C. difficile* strains and assist with the diagnosis of CDI.

Table 1: Comparison to predicate device.

Characteristic	ImmunoCard C. difficile GDH	TECHLAB C. DIFF QUIK CHEK®
Test Format	Rapid EIA	Rapid EIA
Intended Use		
Qualitative/Quantitative	Qualitative	Qualitative
Target Antigen	*Clostridium difficile* glutamate dehydrogenase	*Clostridium difficile* glutamate dehydrogenase
Screening, Diagnostic, or Identification Test	Screening	Screening
Specimen Types		
Human Stool Unpreserved	Yes	Yes
Reagents/Components	ImmunoCard C. difficile GDH Test Cards ImmunoCard C. difficile GDH Enzyme Conjugate ImmunoCard Wash Buffer I ImmunoCard Substrate I ImmunoCard C. difficile GDH Sample Diluent/Negative Control ImmunoCard C. difficile GDH Positive Control Plastic transfer pipettes	Membrane Devices Enzyme Conjugate Wash Buffer Substrate Diluent Positive Control Disposable plastic transfer pipettes
Diagnostic Marker		
Antibody	Yes	Yes
Antibody Sources		
Test Card	Rabbit polyclonal	Polyclonal
Enzyme Conjugate	Mouse monoclonal	Mouse monoclonal
Sample Preparation		
Unpreserved liquid/semi-solid stool	1. 25 µL of thoroughly mixed stool into 200 µL Sample Diluent. Vortex for 10 seconds. 2. Add 3 drops of Enzyme Conjugate to the sample. 3. Incubate diluted sample at 20-26 C for 15 minutes.	1. 1 drop of Enzyme Conjugate into 500 µL Diluent 2. 25 µL specimen into Diluent-Conjugate mixture. Mix with transfer pipette.
Solid stool	1. Add ~2mm diameter portion of thoroughly mixed stool into 200 µL Sample Diluent and vortex for 10 seconds. 2. Add 3 drops of Enzyme Conjugate to the sample.	1. Add 500 µL Diluent to a clean tube. 2. Add 1 drop Conjugate to the Diluent tube. 3. Transfer ~2mm diameter portion of specimen into the Diluent-Conjugate mixture and emulsify the specimen using the applicator stick.
Testing Time	Approximately 25 minutes	Approximately 25 minutes
Equipment		
General Laboratory Equipment	Vortex Interval timer Applicator sticks Small test tubes Disposable latex gloves	Pipettor and tips Vortex Interval timer Applicator sticks Small test tubes Disposable latex gloves
Reading Method	Visual	Visual

Table 1: Comparison to predicate device contd.

Results Interpretation		
Visual Read	**Negative:** Blue color in the CONTROL reaction port only. **Positive:** Blue color in the TEST and CONTROL reaction ports. **Invalid:** No detectable blue color in the CONTROL reaction port or a blue ring on the plastic frame surrounding the TEST port during the test procedure.	**Negative:** Single blue line visible on the CONTROL side of the reaction window only. **Positive:** Blue line visible on the TEST side along with a blue line visible on the CONTROL side. **Invalid:** Single line visible on the TEST side of the reaction window or no lines visible in the reaction window.

Performance Comparison, Non-Clinical Tests

Analytical Sensitivity

Sensitivity studies were designed to determine with 95% confidence the analytical limit of detection (LoD) of *C. difficile* GDH antigen diluted in a human stool matrix. The analytical sensitivity of this assay was based on 45 replicates for each measurand and with a stated probability (95%) of obtaining positive responses at the following levels of the measurand when spiked in stool: 10 ng/mL.

Interference Testing

Selected drugs and other non-microbial substances that might be present in stool samples from healthy persons or patients suspected of having *C. difficile* infection were added to a natural negative and a contrived positive stool sample. The contrived positive sample was prepared by spiking a confirmed negative sample with *C. difficile* GDH at 10 ng/mL, the limit of detection for this assay. Potentially interfering substances were added at final concentrations of 5% V/V or greater. Dilution Controls for each sample were prepared by adding a phosphate-buffered saline solution in place of the potentially interfering substance. Each sample was tested in triplicate.

The following substances, at the specified saturated solvent/diluent concentrations, do not interfere with ImmunoCard *C. difficile* GDH test results in the final concentrations listed: Barium sulfate (5 mg/mL), Fecal fat (2.65 mg stearic acid and 1.3 mg palmitic acid/mL), Hemoglobin (3.2 mg/mL), Imodium AD® (Loperamide HCl) (6.67 x 10^{-3} mg/mL), Kaopectate® (Bismuth subsalicylate) (0.87 mg/mL), Metronidazole (12.5 mg/mL), Mucin (3.33 mg/mL), Mylanta® (Aluminum hydroxide w/ magnesium hydroxide) (4.2 mg/mL), Pepto-Bismol® (Bismuth subsalicylate) (0.87 mg/mL), Polyethylene glycol (79.05 mg/mL), Prilosec® (Omeprazole) (0.5 mg/mL), Simethicone (0.625 mg/mL), Tagamet® (Cimetidine) (0.5 mg/mL), Tums® (Calcium carbonate) (5.0 mg/mL), Vancomycin HCl (2.5 mg/mL), Whole blood (40%), White blood cells (5%).

Cross-reactivity Study

Potentially crossreactive microorganisms that might be present in stool samples from healthy persons or patients suspected of having *C. difficile* associated disease were added to a pooled negative and contrived positive sample. The contrived positive specimen was prepared from a pool of donor stools that was confirmed negative. The contrived positive sample was prepared by spiking a confirmed negative sample with *C. difficile* GDH at 10 ng/mL, the limit of detection for this assay. Potentially cross-reactive microorganisms were added at a final concentration of 1.2 x 10^{8} CFU/mL (bacteria or fungi) or a final concentration greater than 1 x 10^{5} $TCID_{50}$ /mL (viruses). Dilution

controls for each sample were prepared by adding a saline solution in place of the potentially cross-reactive organisms.

The following microorganisms, at the indicated concentrations, do not interfere with ImmunoCard *C. difficile* GDH test results: *Aeromonas hydrophila, Bacillus cereus, Bacillus subtilis, Bacteroides fragilis, Campylobacter coli, Campylobacter fetus, Campylobacter jejuni, Candida albicans, Citrobacter freundii, Clostridium bifermentans, Clostridium butyricum, Clostridium haemolyticum, Clostridium histolyticum, Clostridium novyi, Clostridium perfringens, Clostridium septicum, Clostridium sordellii, Clostridium sporogenes, Clostridium tetani, Enterobacter aerogenes, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Escherichia coli 0157:H7, Escherichia hermannii, Escherichia fergusonii, Helicobacter pylori, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Porphyromonas asaccharolytica, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens,* Salmonella Group B, Salmonella Group C, Salmonella Group D, Salmonella Group E, *Serratia liquifaciens, Serratia marcescens, Shigella boydii, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Vibrio parahaemolyticus, Yersinia enterocolitica,* Adenovirus Type 40, Adenovirus Type 41, Coxsackievirus Strain B4, Echovirus Strain 30, Rotavirus Strain WA.

Stool spiked with Staphylococcus aureus (Cowan Strain I) were found to be cross-reactive with ImmunoCard *C. difficile* GDH.

Strain Reactivity

The following *C. difficile* stock cultures from different sources were tested and produced positive reactions at a concentration of 1.2 x 107 CFU/mL with the ImmunoCard *C. difficile* GDH assay:

Toxigenic *C. difficile* strains: 8864, 10463, 43598, 2004052, 2004111, 2004118, 2004205, 2004206, 2005070, 2005257, 2005325, 2006240, 2007431, 2007435, 2007858, 2008016, 2008029, 2008162, 2008188, 2008341, 2008351, 2009018, 2009065, 2009066, 2009099, 2009132, 2009155, 2009277, B1, BI17, BI8, BK6, CF1, G1, J7, K12, Y1

Non-toxigenic *C. difficile* strains: 11186, 234, 586, 611, 620, 2C62, 2C165, C122, UNC19904, X15076

Performance Comparison, Clinical Tests

Clinical trials for the ImmunoCard *C. difficile* GDH assay were conducted April – June 2011. Performance characteristics of the ImmunoCard *C. difficile* GDH assay were determined by comparison to bacterial *C. difficile* culture. Independent clinical test sites located in the Midwestern, Southeastern, Southwestern, and Western regions of the United States evaluated a total of 975 qualified patient samples; all samples were prospectively collected. Samples were collected from 446 (45.7%) males and 529 (54.3%) females and categorized as solid (17.1%), semi-solid (50.8%), bloody (0.5%) and watery (31.5%). The age groups of patients range from 14 days to 111 years. No differences in test performance were observed based on patient age, gender, or geographic location. Overall sensitivity was determined to be 97.6% (95% CI: 93.3 – 99.2%). Overall specificity was determined to be 87.0% (95% CI: 84.6 – 90.1%). Subsequent tables show overall assay performance as well as performance by clinical site and patient age.

Table 2: Performance Characteristics for ImmunoCard C. difficile GDH

Culture	ImmunoCard C. difficile GDH		
	Positive	Negative	Total
Positive	124	3	127
Negative	110	738	848
Total	234	741	975
			95% CI
Sensitivity	124/127	97.6%	93.3 - 99.2%
Specificity	738/848	87.0%	84.6 - 90.1%
Correlation	862/975	88.4%	86.2 - 90.3%

Table 3: Performance Characteristics by Site

Clinical Trial Site	ImmunoCard C. difficile GDH/Culture	% Sensitivity	95% CI	ImmunoCard C. difficile GDH/Culture	% Specificity	95% CI
Site 1	32/32	100.0%	89.3 - 100.0%	165/205	80.5%	74.5 – 85.3%
Site 2	39/41	95.1%	83.9 – 98.7%	257/290	88.6%	84.4 – 91.8%
Site 3	35/36	97.2%	85.8 - 99.5%	140/168	83.3%	77.0 – 88.2%
Site 4	8/8	100.0%	67.6 - 100.0%	76/80	95.0%	87.8 - 98.0%
Site 5	10/10	100.0%	72.2 - 100.0%	100/105	95.2%	89.3 – 97.9%

Table 4: Performance Characteristics by Patient Age

Patient Age	ImmunoCard C. difficile GDH/Culture	Sensitivity %	95% CI	ImmunoCard C. difficile GDH/Culture	Specificity %	95% CI
≤ 5 years	41/41	100.0%	91.4 – 100.0%	129/168	76.8%	69.8 – 82.5%
6 – 21 years	30/31	96.8%	83.8 – 99.4%	179/208	86.1%	80.7 – 90.1%
22-59 years	21/22	95.5%	78.2 – 99.2%	213/233	91.4%	87.1 – 94.4%
≥ 60 years	32/33	97.0%	84.7- 99.5%	217/239	90.8%	86.5 – 93.8%

Reproducibility

Reproducibility panels were performed by three clinical laboratories using blinded coded panels. Samples were randomly sorted within each panel to mask identities. Each panel consisted of 3 contrived moderately positive specimens, 3 contrived low positive samples, 3 contrived high negative specimens, and 1 natural negative specimen. Panels were tested at three independent laboratories by two operators at each laboratory, twice each day over 5 non-consecutive days. The overall correlation for the ImmunoCard *C. difficile* GDH reproducibility study was 99.7% (98.1 – 99.9%). The correlation between expected and achieved results for the moderate positive, low positive and negative specimens was 100.0% (98.2 – 100.0%). The correlation for the high negative specimen was 98.9% (94.0 – 99.8%). Tables 5-7 contain the reproducibility data for the 3 sites.

Table 5: Site 1 Reproducibility Data, Lot 716050B003

Sample ID	Sample Qual. Result	Day 1 Run 1 (EK)*	Day 1 Run 2 (EEG)*	Day 2 Run 1 (EK)*	Day 2 Run 2 (EEG)*	Day 3 Run 1 (EK)*	Day 3 Run 2 (EEG)*	Day 4 Run 1 (EK)*	Day 4 Run 2 (EEG)*	Day 5 Run 1 (EK)*	Day 5 Run 2 (EEG)*
Positive Control	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Negative	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	83.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: Pos = Positive; Neg = Negative

* Initials of person performing testing.

Interpretation of Results:

Positive Test Result: Blue color in the TEST and CONTROL reaction ports.

Negative Test Result: Blue color in the CONTROL reaction port only.

Invalid Test Results: No detectable blue color in the CONTROL reaction port or a blue ring on the plastic frame surrounding the TEST (upper right) port during the test procedure.

Table 6: Site 2 Reproducibility Data, Lot 716050B001

Sample ID	Sample Qual. Result	Day 1 Run 1 (JM)*	Day 1 Run 2 (DS)*	Day 2 Run 1 (JM)*	Day 2 Run 2 (DS) *	Day 3 Run 1 (JM)*	Day 3 Run 2 (DS)*	Day 4 Run 1 (JM)*	Day 4 Run 2 (DS)*	Day 5 Run 1 (JM)*	Day 5 Run 2 (DS)*
Positive Control	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: Pos = Positive; Neg = Negative

* Initials of person performing testing.

Interpretation of Results:

Positive Test Result: Blue color in the TEST and CONTROL reaction ports.

Negative Test Result: Blue color in the CONTROL reaction port only.

Invalid Test Results: No detectable blue color in the CONTROL reaction port or a blue ring on the plastic frame surrounding the TEST (upper right) port during the test procedure.

Table 7: Site 3 Reproducibility Data, Lot 716050B002

Sample ID	Sample Qual. Result	Day 1 Run 1 (KE)*	Day 1 Run 2 (LS)*	Day 2 Run 1 (KE)*	Day 2 Run 2 (LS) *	Day 3 Run 1 (KE)*	Day 3 Run 2 (LS)*	Day 4 Run 1 (KE)*	Day 4 Run 2 (LS)*	Day 5 Run 1 (KE) *	Day 5 Run 2 (LS)*
Positive Control	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Positive	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Negative 1	Negative	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: Pos = Positive; Neg = Negative

* Initials of person performing testing.

Interpretation of Results:

Positive Test Result: Blue color in the TEST and CONTROL reaction ports.

Negative Test Result: Blue color in the CONTROL reaction port only.

Invalid Test Results: No detectable blue color in the CONTROL reaction port or a blue ring on the plastic frame surrounding the TEST (upper right) port during the test procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Meridian Bioscience, Inc.
c/o Susan Bogar
Product Quality Assurance Manager
3471 River Hills Drive
Cincinnati, OH 45244

DEC 16 2011

Re: K112048
Trade/Device Name: ImmunoCard™ *C. difficile* GDH Assay
Regulation Number: 21 CFR § 866.2660
Regulation Name: Microorganism Differentiation and Identification Device
Regulatory Class: Class I
Product Codes: MCB
Dated: December 7, 2011
Received: December 8, 2011

Dear Ms. Bogar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

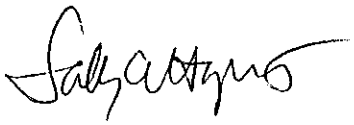
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Devices
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use Form

510(k) Number (if known): K112048

Device Name: ImmunoCard *C. difficile* GDH

Indications for Use:

ImmunoCard *C. difficile* GDH is a rapid qualitative enzyme immunoassay screening test to detect *Clostridium difficile* antigen, glutamate dehydrogenase, in fecal specimens from persons suspected of having *C. difficile* infection (CDI). This test does not distinguish between toxigenic and non-toxigenic strains of *C. difficile*. Samples from patients that produce positive results with this test must be further tested with an assay designed to detect toxigenic *C. difficile* strains and assist with the diagnosis of CDI.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety.

510(k) K112048